UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,192	09/25/2006	Mette Gronborg	50721/006002	5685

21559 7590 08/23/2011

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
HAYES, ROBERT CLINTON	
ART UNIT	**PAPER NUMBER**
1649	

NOTIFICATION DATE	DELIVERY MODE
08/23/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/594,192	GRONBORG ET AL.	
	Examiner	Art Unit	
	ROBERT C. HAYES	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *92,129,132 and 133* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *92,129,132 and 133* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/1/11;6/30/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed 6/19/11 has been entered.

2. Applicant's arguments filed 9/19/11 have been fully considered but they are not deemed to be persuasive.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 92 and 132-133 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper NOs: 20090618, 20101001 & 20110318, and as follows. **This is a written description rejection**.

Applicants argue on pages 4-6 of the response that page 21 describes "preferred variants of NsG33 [that] differ from the wildtype sequence by one or more conserved and/or semiconservative amino acid substitutions", that "[t]he Clustal W alignment in Figure 3a and Figure 3b can be used to predict which amino acid residues can be substituted without affecting the biological activity of the protein" (which is irrelevant to meeting the written description requirements under 35 U.S.C. 112, 1st paragraph, even if one knew what a Clustal W alignment entailed, versus the paucity of information provided on page 21 within the instant specification

concerning this term), and then again present their interpretation of the findings of the courts in Fiers and Univ. of California. In contrast to Applicants' arguments, only new claims 132 & 133 attempt to recite (although poorly) those amino acid residues that could not be substituted (i.e., possibly establishing a structure/functional correlation, if any correlation with treating Huntington's disease was also described within the specification, which it is not). Taken a different way, merely arguing that "accordingly, the specification identifies the amino acids responsible for the activity of NsG33", but not indicating a single "activity of NsG33" for treating Huntington's disease supports the Examiner's position. The issue still remains that the claims are directed to "treating Huntington's disease…" with variant proteins (i.e., at least 95% identity) of SEQ ID NO: 4, in which only cysteine residues are recited as critical. In contrast, not a single *critical amino acid residue* required for successfully "treating" Huntington's disease is described, which then would not be "substituted". In other words, no correlation between structure and function for what critical amino acids actually would accomplish successfully "treating" Huntington's disease is described. Nor can such be reasonably predicted by one of ordinary skill in the art based upon the prophetic and generalized teachings of the instant specification. Thus, as previously made of record, the specification fails to describe a single critical amino acid residue required for any *definable function* in the claimed genus; analogous to the situation decided in *Fiers v. Revel*, and *Univ. California v. Eli Lilly and Co.,* wherein the current claims merely constitute an invitation for others to discover a representative number of species, in order to reasonably extrapolate to the claimed genus, with a known or disclosed *correlation between function and structure*, or by a combination of such identifying characteristics, which has not been provided within the instant specification. Thus, Applicants

are clearly not in possession of using the claimed genus of NsG33 polypeptides required to practice the currently claimed method, and for the reasons previously made of record. See again MPEP 2163.

5. Claims 92, 129 & 132-133 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a definable population of neurons affected in Huntington's disease with a structurally and functionally definable NsG33 polypeptide with recited functional characteristics, does not reasonably provide enablement for treating unknown function limitations in unknown neuronal populations in patients with Huntington's disease using structurally and functionally undefined NsG33 polypeptides (i.e., as it relates to "at least 95% identity…"), or biologically functional equivalents thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons made of record in Paper NOs: 20090618, 20101001 & 20110318, and as follows.

Applicants argue on pages 6-8 of the response that "[t]he Office's requirement that in order to enable the 'treatment of Huntington's disease' Applicants must further enable 'curing' Huntington's disease is not supported by law", which is actually an over simplification and mischaracterization of the rejection of record. In contrast, the Examiner was merely pointing out the state of the art, the lack of guidance provided within the instant specification, and the broadness of the current claims, consistent with that held by the court in *In re Wands,* and therefore, what the skilled artisan would reasonably need to know in order to know how to make and use (i.e., enable) the currently broadly "claimed" invention.

Applicants then argue that "administration of NsG33 is useful to protect the neurons from further degeneration", and then refer to Example 15 of the specification. However, no population of neurons to be treated are recited in the claims, and no assayable functional language, such as increasing survival of striatal neurons (if proper support could be found) is recited within the claims, which could enable the invention. In other words, Applicants' current claims are not commensurate in scope with what would enable the invention, for the reasons previously made of record. Again, as it relates to Applicants' comment on page 8 of the response, although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Thus, Applicants' arguments remain not persuasive.

6. Claims 92, 129 & 132-133 are rejected under 35 U.S.C. 102(b) as being anticipated by Tang et al/ HYSEQ, INC (WO 01/57190; IDS Ref # B6), and for the reasons made of record in Paper NOs: 20090618 & 20110318, and as follows.

Applicants argue on pages 8-9 of the response that "[i]n the chemical arts, a prior art reference teaching of genus [*sic*] may only anticipate a species if the species can 'at once be envisaged' from the genus. M.P.E.P. 2131.02", and then argues that "a prior art reference must provide an enabling disclosure of the desired subject matter in order for this prior art to be an anticipating reference" apparently based upon "the multitude of genes and diseases disclosed". However, in the instant case, Tang et al. specially teach using the species NsGG33 of SEQ ID NO: 4 of the instant invention (i.e., Tang's SEQ ID NO: 1401 protein) to "treat Huntington's disease", as recited in the claims. Therefore, in contrast to Applicants' assertions, no genus is

relied upon for the instant rejection; wherein Tang teaches the same scope of treatment as recited in the current claims. In conclusion, because Tang specifically teaches the skilled artisan to use the protein identical to SEQ ID NO: 4 to "treat Huntington's" disease patients, as claimed, Tang's teachings are further enabling within its own right; absent evidence to the contrary, because the only active step is the administration of the polypeptide identical to SEQ ID NO: 4 to Huntington's patients. Whether other polypeptides are described by Tang is immaterial because Tang still teaches use of the polypeptide identical to SEQ ID NO: 4 to treat Huntington's patients. Thus, Applicants' arguments are without merit, and simply mischaracterize the teachings of Tang.

In summary, Tang et al teach administering the polypeptide of SEQ ID NO: 1401, which is 100% identical to SEQ ID NO: 4 of the instant invention (e.g., see pgs 4-5, 28-29 & 65-66), to treat nervous system disorders (section 4.10.17; pgs. 60-61), in which page 61 (line 3) specifically lists treating Huntington's chorea (i.e., as it relates to claim 92 & 94); thereby, anticipating all claims.

7. New claims 132-133 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of "having all amino acid residues marked in Figure 3a as fully conserved/strongly conserved" is confusing because it isn't clear if all amino acids residues are now suppose to be "fully conserved" (as it relates to claim 132), or "strongly conserved" as currently recited in claim 133; or what exactly this claim language means, because no figure

legend in the specification describes what markings are "fully conserved" or "strongly conserved". In addition, merely listing 32 amino acids in claim 133 makes little sense on what is "strongly conserved" because no "conserved groups" are listed in relationship to anything meaningful; thereby, making these claim ambiguous and indefinite.

Second, the term "fully conserved" or "strongly conserved" is a relative term which renders the claim indefinite. The term "fully conserved" or "strongly conserved" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Kolker, can be reached on (571) 272-3181. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/ROBERT C. HAYES/
Primary Examiner, Art Unit 1649
August 15, 2011